

**STATE OF NEW MEXICO
COUNTY OF BERNALILLO
SECOND JUDICIAL DISTRICT COURT**

**STATE OF NEW MEXICO, *ex rel.*
NEW MEXICO SOCIETY FOR
ACUPUNCTURE AND ASIAN MEDICINE,**

D-202-CV-2017-00942

Plaintiff,

v.

**KINETACORE HOLDINGS, LLC, EDO ZYLSTRA,
KERI MAYWHORT, JOHN AND JANE DOES,**

Defendants.

COMPLAINT FOR INJUNCTIVE RELIEF

I. INTRODUCTION

1. Plaintiff, the New Mexico Society for Acupuncture and Asian Medicine (“Plaintiff”), is an Albuquerque, New Mexico-based non-profit consisting of trained and licensed acupuncturists that are dedicated to promoting acupuncture and its safe and competent practice.

2. Plaintiff, brings the instant suit pursuant to the New Mexico Medical Practice Act (“New Mexico MP Act”), NMSA 1978, § 61-6-22, to enjoin Defendants, Kinetacore Holdings, LLC (“Kinetacore”), a Kentucky-based “dry needling” training company, its CEO and founder Edo Zylstra (“Zylstra”), and its lead instructor Keri Maywhort (“Maywhort”) from the insertion of acupuncture needles as deep as four inches into humans during for-profit training courses in the use of such needles.

3. The first course is planned for the weekend of February 25th and 26th in Albuquerque, New Mexico, and is called “Functional Dry Needling Level 1” (“Course”).

4. Additional courses are expected to follow.

5. The Course is being marketed to physical therapists that often have no experience whatsoever in the safe and competent use of any needle, let alone in the deep insertion of acupuncture needles.

6. The Course presents a substantial threat to public safety since Course participants are told that they can begin inserting acupuncture needles into their patients “immediately after completion” of the mere 29-hour Course, 19 hours of which are live and 10 hours of which are online.

7. For comparison, New Mexico law requires acupuncturists to have a minimum of 2,400 hours of training, including a minimum of 900 hours of clinical training under direct supervision, before they can begin inserting acupuncture needles into their patients. NMSA 1978, §§ 61-14A-14(A), (A)(2), 61-14A-14.1(A); NMAC § 16.2.7.8(B).

8. The minimal training typical to “Dry needling” has already resulted in a number of serious patient injuries ranging from pneumothoraces (“lung punctures”) to nerve damage.

9. As the American Medical Association (“AMA”) has recently made clear in taking a position critical of dry needling, “[d]ry needling is indistinguishable from acupuncture,” and “[l]ax regulation and nonexistent standards surround this invasive practice. . . . For patients’ safety, practitioners should meet standards required for acupuncturists and physicians.”

American Medical Association. *Physicians take on timely public health issues*. AMA Wire. 2016 June 15. www.ama-assn.org/ama/ama-wire/post/physicians-timely-public-health-issues.

10. Defendants have asserted in prior cases against them that, even though what they refer to as “dry needling” involves the insertion of acupuncture needles into humans for the

purpose of providing therapeutic relief, that they are immune from the training, safety, and licensure requirements that apply to the practice of acupuncture.

11. Defendants generally have based this claim on their assertion that dry needling is based on a “Western medical philosophy” whereas acupuncture is based on “Eastern philosophy.”

12. Defendants have never shown, however, that dry needling involves any different safety risks than the practice of acupuncture.

13. Defendants have been enjoined by both permanent injunctions and temporary restraining orders in at least four different orders from federal and state courts.

14. Absent licensure as an acupuncturist, the insertion of acupuncture needles clearly falls within New Mexico’s broad definition of the “practice of medicine” and is prohibited without a medical license. NMSA 1978, § 61-6-6(J).

15. Defendants’ planned insertion of an acupuncture needle into course participants and other persons constitutes “offering or undertaking to perform an operation or procedure upon a person,” and is prohibited absent a medical license. NMSA 1978, § 61-6-6(J)(4).

16. Defendants’ insertion of acupuncture needles into a person for any therapeutic purpose constitutes “offering or undertaking to diagnose, correct or treat in any manner or by any means, methods, devices or instrumentalities any disease, illness, pain, wound, fracture, infirmity, deformity, defect or abnormal physical or mental condition of a person.” NMSA 1978, § 61-6-6(J)(5).

17. Absent training and licensure as either a medical doctor or acupuncturist, the insertion of acupuncture needles constitutes the unauthorized practice of medicine. Defendants

and their agents are physical therapists and are neither trained nor licensed as medical doctors or acupuncturists.

18. Defendants, therefore, lack legal authority under New Mexico law to insert acupuncture needles, NMSA 1978, § 61-6-6(J), and should be enjoined until such time as they obtain the required training and licensure.

JURISDICTION AND VENUE

19. This court, as a court of general jurisdiction, has jurisdiction over the subject matter and parties. This case arises under NMSA 1978, § 61-6-22, which authorizes “any citizen of any county where any person engages in the practice of medicine as defined by the laws of New Mexico without possessing a valid license to do so, may in accordance with the laws of the state governing injunctions, maintain an action in the name of the state to enjoin such person from engaging in the practice of medicine until a valid license to practice medicine is secured from the board.”

20. Defendants and their personal representatives transact business within the State of New Mexico pursuant to NMSA 1978, § 38-1-16.

21. Defendants offer their Course for the price of \$1,250 and the Course is clearly a service that is part of a business transaction.

22. Defendants’ business transactions in New Mexico also include promoting and advertising the Course in New Mexico to New Mexico residents; accepting payment for the Course from course participants located in New Mexico; communicating with Course participants; providing payment receipts to Course participants; and planning, organizing, and reserving space for the Course.

23. Defendant Kinetacore and one or more of its agents, as well as Defendant Maywhort, will be physically present in New Mexico for the Course.

24. Plaintiff is a citizen of Bernalillo County having been incorporated there and having its principal place of business in Bernalillo County.

25. Venue is proper in Bernalillo County pursuant to NMSA 1978, § 38-3-1(A) and (F) and § 61-6-22 because the conduct alleged to be contrary to law would take place in this county.

PARTIES

26. Plaintiff is a volunteer-run, New Mexico-based non-profit that is dedicated to supporting acupuncture, including its safe and competent practice and accessibility to the public.

27. A key goal of Plaintiff's organization is to protect core values of acupuncture and the paramount value is public safety.

28. Plaintiff's members' ability to attract and maintain patients is significantly and directly affected by the public's comfort or fear with the safety of acupuncture needles.

29. Fear of needles is the single largest factor that limits new patients from experiencing acupuncture.

30. Injuries that result from a lack of training in the proper use of acupuncture directly threaten both Plaintiff's organizational goals and the livelihoods of Plaintiff's members.

31. Plaintiff is based in and incorporated in Albuquerque, New Mexico, and has approximately 25 acupuncturist members.

32. Defendant Kinetacore is a Kentucky-based Limited Liability Company that primarily offers weekend "dry needling" courses around the country to train physical therapists

on the insertion of acupuncture needles.

33. Kinetacore has announced and is actively promoting sales for a weekend course that it plans to hold on February 25th and 26th in Albuquerque, New Mexico, at PT Division.

34. Kinetacore's website currently shows that the Course is "Full."

35. Kinetacore is a proper defendant because its owners, managers, and agents are planning to and, unless enjoined, will engage in the unauthorized practice of medicine in New Mexico as described below.

36. Defendant Zylstra is the founder and CEO of Kinetacore and is also a "Lead Instructor" for Kinetacore.

37. As CEO, Zylstra has authorized and approved holding the Course in Albuquerque, New Mexico.

38. Defendant Maywhort is the Director of Education and a "Lead Instructor" for Kinetacore.

39. Maywhort is also listed as one of the instructors that will teach at the Course.

40. In that role, Maywhort will insert acupuncture needles into humans.

41. Maywhort is not licensed as either a physician or acupuncturist in New Mexico.

42. Defendants John and Jane Does are Course participants whose identities are currently unknown that lack a medical license, or any other professional license, such as an acupuncture license, that would authorize them to insert acupuncture needles into humans.

FACTUAL BACKGROUND

Defendants' Course

43. Plaintiff incorporates all preceding paragraphs.

44. Defendants have announced their intent to offer a weekend course titled "Functional Dry Needling Level 1" on February 25th and 26th in Albuquerque, New Mexico, at the PT Division of the University of New Mexico campus.

45. The Course involves training on the insertion of acupuncture needles into humans.

46. The Course is being marketed to physical therapists.

47. The purpose of the Course is to train physical therapists to insert acupuncture needles into their patients for the purpose of providing therapeutic relief.

48. Physical therapist participants may have no other experience or training with the safe and competent use of acupuncture needles, or the insertion of any needle.

49. The Course will include the use of acupuncture needles of up to four inches in length.

50. Attendees from prior courses have reported inserting acupuncture needles five inches in length shortly after completing the course.

51. During the Course, Defendant Kinetacore's instructors, including, but not limited to, Defendant Maywhort, will insert acupuncture needles into Course participants.

52. Course participants will also insert acupuncture needles into other Course participants during the Course.

53. Physical therapists in New Mexico are not required to have any training or experience in the safe and competent use of needles in order to obtain licensure as physical therapists.

54. The Course is believed to be the first such course offered in New Mexico to physical therapists.

55. At the end of the two-day Course, Course participants will be given a certificate and informed that they are qualified to immediately start inserting acupuncture needles into their patients.

56. In marketing the Course, Defendant Kinetacore promises that Course participants can “[u]se FDN [Functional Dry Needling] immediately after completion of Level 1.”

57. On information and belief, Defendant Kinetacore intends to offer the same or a similar course in New Mexico in the future.

58. In order to acquire a legal license to insert acupuncture needles in New Mexico, an acupuncturist must obtain a minimum of 2,400 hours in training including 900 hours of clinical training. NMSA 1978, § 61-14A-14(A); NMAC § 16.2.7.8(B). Defendants have publicly asserted that they are exempt from state acupuncture licensure laws because dry needling is based on a different philosophy than acupuncture.

Defendants are under court injunctions in multiple cases

59. Defendants Kinetacore, Zylstra, and Maywhort are currently under court injunctions in multiple states related to their dry needling courses and the insertion of acupuncture needles.

60. In 2014, Defendants Kinetacore¹, Zylstra, and Maywhort were permanently enjoined by an order of the Washington Superior Court from inserting acupuncture needles after they held a dry needling course in the Seattle area. *South Sound Acupuncture Ass'n v.*

¹ The Defendant in this case was technically “Kinetacore LLC,” whereas the Defendant in the instant case is “Kinetacore Holdings, LLC.” Defendants continue to advertise and represent themselves under the name “Kinetacore” and, despite the slight name change, defendant Zylstra continues to lead Defendant’s operations as CEO.

Kinetacore, Order for Partial Summary Judgment, Case No. 13-2-35460-8 SEA, (Oct. 10, 2014).

The court held that the insertion of acupuncture needles by physical therapists lacking a medical or acupuncture license constituted “the unauthorized practice of medicine” regardless of whether the defendants in the case referred to it as “dry needling” or “acupuncture.”

61. In 2016, Defendant Zylstra, along with Kinetacore instructors Austin Woods (“Woods”) and Paul Killoren (“Killoren”), were barred from inserting acupuncture needles at a planned demonstration in California pursuant to a temporary restraining order by the Orange County Superior Court. *Int'l Ctr. for Integrative Medicine v. Kinetacore*, Temporary Restraining Order, Feb. 17, 2016, Case No. 30-2016-008-35053-CU-MC-CJC. The court similarly enjoined Defendant Zylstra and his co-defendants from distributing, delivering, or selling acupuncture needles in California.

62. After Defendants Zylstra, Woods, and Killoren transferred the case to the United States District Court, Central District of California, they were permanently enjoined from inserting acupuncture needles within the State of California pursuant to a consent decree approved by the federal court. *Int'l Ctr. for Integrative Medicine v. Kinetacore*, Consent Decree, United States District Court for the Central District of California, Case No. 8:16-cv-00736-JLS-GJS, July 7, 2016.

63. On January 24, 2017, Kinetacore dry needling instructors Woods and Killoren were permanently enjoined again by the King County Superior Court in Washington State and barred from engaging in the insertion of acupuncture needles in Washington State pursuant to a stipulated judgment. The case was not specific to Kinetacore’s Courses, but the stipulated judgment was explicit that the insertion of acupuncture needles was outside the physical therapy

scope of practice and, therefore, constitutes the unlicensed practice of medicine. *Wash. ex rel. Soc'y for Acupuncture Safety v. Killoren*, Stipulated Motion for Entry of Judgment and Order, Case No. 16-2-22927-1 SEA, January 24, 2017.

Dry needling is acupuncture

64. Dry needling is a different term used to describe the practice of acupuncture.

65. Dry needling involves the insertion of needles that are specifically defined as "acupuncture needles" by the U.S. Food and Drug Administration ("FDA"). 21 C.F.R. § 880.5580.

66. Dry needling involves the insertion of needles into the same "trigger points" that have been recognized in acupuncture as reactive (painful) acupuncture points, also known as "ashi points," for over 2,000 years.

67. Dry needling is intended for the same purpose as acupuncture: therapeutic relief.

68. In taking a position critical of dry needling, the AMA recently stated, "Dry needling is indistinguishable from acupuncture . . ." American Medical Association. *Physicians take on timely public health issues*. AMA Wire, 2016 Jun 15. <http://www.ama-assn.org/ama/ama-wire/post/physicians-timely-public-health-issues>.

U.S. Food and Drug Administration's regulation of acupuncture needles

69. The needles used in dry needling are a medical device that the FDA has specifically defined as an "acupuncture needle." 21 C.F.R. § 880.5580(a).

70. FDA regulations define "acupuncture needles" by clearly stating that "[a]n acupuncture needle is a device intended to pierce the skin *in the practice of acupuncture*." *Id.* (emphasis added).

71. The FDA regulates acupuncture needles as a Class II prescription medical device.21 C.F.R. §§ 880.5580(b)(1), 801.109.

72. The FDA has specifically stated that sale of acupuncture needles can be made only “to *qualified practitioners of acupuncture* as determined by the states.” 61 Fed. Reg. 64616 (Dec. 6, 1996) (emphasis added).

73. While Plaintiffs cannot legally enforce Defendants’ violations of the Food, Drug, and Cosmetic Act to enforce violations of FDA’s regulations, Defendants regularly assert that they are not practitioners of acupuncture and have no credible legal argument that they are “qualified practitioners of acupuncture” under state law.

74. Labeling on boxes of acupuncture needles generally states: “Caution: Federal law restricts this device to sale by or on the order of *qualified practitioners of acupuncture* as determined by the States.”

75. Needles used in the Course are “acupuncture needles” as the term is defined by the FDA.

Defendants’ dry needling courses would cause irreparable injury

76. As the FDA has recognized, the risks of acupuncture needles include “sepsis [a dangerous complication caused by the body’s response to an infection, which can lead to tissue damage, organ failure, and death], excessive trauma, and perforation of blood vessels and organs.” 61 Fed. Reg. 64616 (Dec. 6, 1996).

77. A number of serious injuries, including pneumothoraces (lung punctures), and other adverse events have been caused by physical therapists with little to no training inserting acupuncture needles into their patients.

78. The insertion of acupuncture needles during the Course by persons that possess neither the training nor licensure to safely and competently insert those needles poses a substantial risk of irreparable harm to public safety, the organizational interests of Plaintiffs in the safe practice of acupuncture, and the livelihoods of Plaintiffs' members.

79. Injuries that result from the improper use of acupuncture needles directly undermine public confidence in the safety of acupuncture needles, regardless of whether the person using the needle refers to him or herself as "dry needling" or "practicing acupuncture."

80. There is a substantial risk of harm to Course participants caused by acupuncture needle insertion during the Course.

81. There is an even more significant risk of harm posed by the 30 physical therapists that will attend the Course (named here as John and Jane Doe Defendants) and then immediately thereafter start inserting acupuncture needles of up to five inches in length into their patients.

82. Even assuming that the 30 course participants each treat only 20 to 30 different patients during the pendency of this case, that would total 600 to 900 patients exposed to the risks of persons who may have had no more than 29 hours of training in the use of acupuncture needles.

LEGAL OVERVIEW OF THE NEW MEXICO MEDICAL PRACTICE ACT AND NEW MEXICO PHYSICAL THERAPY ACT

83. The practice of medicine is defined broadly under New Mexico law to include "offering or undertaking to perform an operation or procedure upon a person" and "offering or undertaking to diagnose, correct or treat in any manner or by any means, methods, devices or instrumentalities any disease, illness, pain, wound, fracture, infirmity, deformity, defect or abnormal physical or mental condition of a person." NMSA 1978, § 61-6-6(J)(4), (5).

84. The New Mexico MP Act allows Plaintiff to bring an action for an injunction against a person that is practicing medicine without a required license. It states:

The attorney general, the prosecuting attorney, the board or *any citizen* of any county where any person engages in the practice of medicine as defined by the laws of New Mexico without possessing a valid license to do so may, in accordance with the laws of the state governing injunctions, maintain an action in the name of the state to enjoin such person from engaging in the practice of medicine until a valid license to practice medicine is secured from the board. NMSA 1978, § 61-6-22 (emphasis added).

85. New Mexico law exempts physical therapists, acupuncturists, and other licensed health care professionals from the requirement for a medical license if they are practicing within the legislatively defined scope of practice “as defined and limited under their respective licensing law.” NMSA 1978, § 61-6-17(F)(9), (10).

86. The insertion of acupuncture needles does not fall within the physical therapy scope of practice adopted by the New Mexico Legislature. NMSA 1978, § 61-12D-3(I).

87. The insertion of acupuncture needles by a physical therapist that lacks a license as a medical doctor or acupuncturist, therefore, constitutes the unlicensed practice of medicine.

88. Nothing in the New Mexico Physical Therapy Act (“New Mexico PT Act”) reflects an intent by the New Mexico Legislature to authorize the invasive insertion of a medical device, let alone an acupuncture needle of up to five inches in length.

89. The New Mexico PT Act defines the scope of practice for physical therapy as:

(1) examining and evaluating patients with mechanical, physiological and developmental impairments, functional limitations and disabilities or other health-related conditions in order to determine a physical therapy diagnosis, prognosis and planned therapeutic intervention; (2) alleviating impairments and functional limitations by designing, implementing and modifying therapeutic interventions that include therapeutic exercise; functional training in self-care and community or work reintegration; manual therapy techniques, including soft tissue and joint mobilization

and manipulation; therapeutic massage; assistive and adaptive devices and equipment; bronchopulmonary hygiene; debridement and wound care; physical agents; mechanical and electrotherapeutic modalities; and patient-related instruction; (3) preventing injury, impairments, functional limitations and disability, including the promotion and maintenance of fitness, health and quality of life in all age populations; and (4) engaging in consultation, testing, education and research.” NMSA 1978, § 61-12D-3(I) (1997).

90. The New Mexico PT Act also provides that “[t]he practice of physical therapy is declared to affect the public interest and that act shall be liberally construed so as to accomplish the purpose stated in that act.” NMSA 1978, § 61-12D-2.

91. New Mexico’s acupuncture statute in key part specifically describes acupuncture as “the surgical use of needles inserted into and removed from the body . . .” NMSA 1978, § 61-14A-3(A).

92. The New Mexico Acupuncture and Oriental Medicine Practice Act specifically does not require an acupuncture license for “the use of needles for diagnostic purposes and the use of needles for the administration of diagnostic or therapeutic substances by licensed health care professionals.” NMSA 1978, § 61-14A-6(7).

93. The insertion of acupuncture needles by physical therapists is not for the purpose of “diagnosis” and does not administer a “diagnostic or therapeutic substance,” such as a drug or intravenous solution.

94. While the fact that “dry needling” clearly falls within the plain definition of “acupuncture” under New Mexico law highlights the lack of legislative intent to authorize physical therapists to engage in the same act, the Court need not find that “dry needling” constitutes “acupuncture” in order to reach the core issue: the physical therapy scope of practice does not include the invasive insertion of acupuncture needles.

CAUSE OF ACTION

Count I – Practice of medicine without a valid medical license

95. Plaintiff incorporates all preceding paragraphs.
96. The insertion of acupuncture needles by Defendants, whether referred to as “dry needling” or any other name, constitutes the practice of medicine under the New Mexico MP Act. NMSA 1978, § 61-6-6(J)(4), (5).
97. Defendants’ insertion of acupuncture needles into humans without licensure as a medical doctor, acupuncturist, or any other profession that authorizes the insertion of acupuncture needles constitutes the unlicensed practice of medicine in violation of the New Mexico MP Act and is subject to injunction. NMSA 1978, § 61-6-22.

98. Defendants’ physical therapy licenses do not exempt them from the licensure requirements of the New Mexico MP Act because the insertion of acupuncture needles is outside the scope of practice the New Mexico Legislature has adopted for physical therapy. NMSA 1978, § 61-12D-3(I).

WHEREFORE, Plaintiff respectfully requests that the Court:

- A. Issue a permanent injunction by prohibiting the Defendants from the insertion of acupuncture needles, or any similar needle, into any person during the planned Course on February 25th and 26th on the grounds that the insertion of such needles constitutes the unlicensed practice of medicine since it is not authorized in the physical therapy scope of practice;
- B. Issue a permanent injunction prohibiting the Defendants from the insertion of acupuncture needles, or any similar needle, during future dry needling courses, or at any other time and place within the State of New Mexico;
- C. Should any course occur prior to resolution of this case, issue a permanent injunction

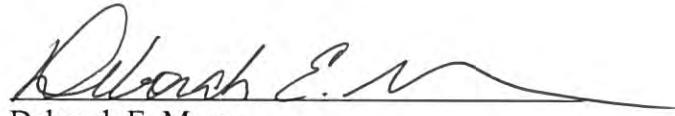
prohibiting the Defendants John and Jane Does from inserting acupuncture needles into any person unless they obtain licensure for the practice of medicine, acupuncture, or another profession authorizing the insertion of acupuncture needles;

D. Award Plaintiff's attorney fees, costs, and other relief that the Court deems proper.

Respectfully Submitted,

MONTGOMERY & ANDREWS, P.A.

By



Deborah E. Mann
Montgomery & Andrews, P.A.
100 Sun Ave NE, Suite 400
Albuquerque, NM 87109
Phone: (505) 884-4200
Fax: (505) 888-8929
dmann@montand.com

-and-

Brent Foster, OSB # 992637, *pro hac vice*
Attorney at Law
1767 12th St # 248
Hood River, OR 97031
Phone: (541) 380-1334
foster.brent@ymail.com

*Attorneys for New Mexico Society for Acupuncture
and Asian Medicine*